4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6765]

Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices." This guidance is intended to update and provide clarity on the replacement reagent and instrument family policy for manufacturers of in vitro diagnostic devices and FDA staff to promote consistent application of the concepts in this guidance. Specifically, it addresses a manufacturer's application of an assay that was previously cleared for use based on performance characteristics when used with a specified instrument to an additional instrument that was previously cleared, or that is a member of an instrument family from which another member has been previously cleared. This document supersedes the final guidance "Replacement Reagent and Instrument Family Policy" issued on December 11, 2003.

DATES: The announcement of the guidance is published in the *Federal Register* on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-D-6765 for "Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices" to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration,

10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Scott McFarland, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3572, Silver Spring, MD 20993-0002, 301-796-6217.

SUPPLEMENTARY INFORMATION:

I. Background

In 2003, FDA issued updated guidance on the "Replacement Reagent and Instrument Family Policy" for in vitro diagnostic (IVD) devices. The 2003 guidance described a mechanism for manufacturers to follow when applying an assay that was previously cleared based on performance characteristics when used with a specified instrument to an additional instrument that is either cleared or a member of an instrument family from which another instrument was previously cleared. Through the approach described in the 2003 guidance, manufacturers established sufficient control to maintain the level of safety and effectiveness demonstrated for the cleared device for these types of modified devices, when evaluated against predefined acceptance criteria using a proper validation protocol, without submission of a premarket notification (510(k)).

This guidance is intended to update and provide clarity on the replacement reagent and instrument family policy for manufacturers of IVD devices and FDA staff to promote consistent application of the concepts in this guidance. Specifically, it addresses a manufacturer's application of an assay that was previously cleared for use based on performance characteristics when used with a specified instrument to an additional instrument that was previously cleared, or that is a member of an instrument family from which another member has been previously cleared. This document supersedes the final guidance "Replacement Reagent and Instrument Family Policy" issued on December 11, 2003.

A notice of availability of the draft guidance appeared in the *Federal Register* of December 18, 2017 (82 FR 60024). FDA considered comments received and revised the guidance as appropriate in response to the comments, including changing the scope of the guidance such that, in certain limited situations, point of care IVD devices could be within the scope of the guidance rather than being expressly identified as outside the scope of the guidance, the addition of flowcharts, updates to examples, and further clarification of terminology.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the replacement reagent and instrument family policy for in vitro diagnostic devices. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products. This guidance document is also available at https://www.regulations.gov and https://www.fda.gov/regulatory-information/search-fda-guidance-documents. Persons unable to download an electronic copy of "Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 950 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is

not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the following table:

21 CFR Part; Guidance; or FDA Form	Topic	OMB Control No.
807, subpart E	Premarket notification	0910-0120
"Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff"	Q-submissions	0910-0756
800, 801, and 809	Medical Device Labeling Regulations	0910-0485
"Administrative Procedures for Clinical Laboratory Improvement Amendments (CLIA) of 1988 Categorization"	CLIA Categorization	0910-0607
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910-0073

Dated: August 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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